REMARKS/ARGUMENTS

This response is to the Non-Final Office Action dated January 12, 2007. Claims 1, 2, 4-7, 10, 11 and 13-21 are pending in the application. Claims 20 and 21 are withdrawn from consideration and are subject to a restriction requirement. Claims 1, 2, 4-7, 10, 11 and 13-19 are rejected. Claims 1, 5, 10 and 18 have been amended, and no claims have been added or cancelled.

Claim Rejections Under 35 U.S.C. § 112

Claim 10 was rejected under 35 U.S.C. § 112, second paragraph, for reciting the limitation "the level of oxygen" in line 1 and having insufficient antecedent basis for this limitation. Claim 10 has herewith been amended to recite "wherein the oxygen in the superoxygenated composition has a concentration from about 45 parts per million to about 220 parts per million."

Withdrawal of this rejection is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 4, 5, 6, 13, 20, and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US Patent No. 5,766,490). According to the Office Action:

> Taylor et al. teaches a process to enable the production of water highly enriched with oxygen with a higher concentration of dissolved solved oxygen and with longer retention of the dissolved oxygen in the water (col. 2, lines 41+). The superoxygenated water of Taylor can be advantageously employed in, for example, increasing the oxygen content of blood and tissues; oxygenation of wounds to increase the rate of healing and to reduce infections; oxygenated organ transplant storage media; tumor oxygenation for radiation therapy and chemotherapy; lung bypass by oxygenated liquids in case of pulmonary deficiencies; carbon monoxide poisoning; mouthwashes, dentrifices; topical, including cosmetic, treatment media; contact lens treating solutions; and cell level therapeutic applications (col. 5, lines 26+). Taylor discloses that oxygen is distributed in the water as bubbles and also as some amount of oxygen dissolved in the water (col. 7, lines 18+). Claim 1 recites the limitation "for a time sufficient to increase the subepithelial partial oxygen pressure from about 30% to about 12)% above baseline pO_2". The time is considered inherent since the application is the same way "topical" and applied to the same lesions "wounds" and for the same reason which is

enhancing healing and because the pharmaceutical vehicle comprising the oxygen would inherently be left on the lesion for a suitable time that will give oxygen bubbles the chance to work sufficiently on the tissue.

Claims 20 and 21 have been withdrawn. Independent claim 1 (from which claims 2, 4-7, 10, 11, and 13-19 depend) has been amended herein to recite "a superoxygenated composition of oxygen microbubbles consisting essentially of oxygen in a pharmaceutically acceptable vehicle directly to a tissue surface selected from the group consisting of skin and mucous membranes for a time sufficient to increase the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO_2." Claim 1 has been amended thus to more clearly indicate the novel ability of the methods and compositions of the invention to topically deliver oxygen that diffuses through tissue (e.g., skin) and that is effective at oxygenating subepithelial tissue. Support for the limitation of "to increase the partial oxygen pressure at least about 2 mm beneath the tissue surface" can be found in Example 2 beginning on page 20, and in particular on line 16, page 30[1].

Taylor et al. does not teach all the limitations of claim 1 (and thus dependent claims 2, 4-7, 10, 11, and 13-19) as amended. For example, Taylor et al. does not teach a method of increasing tissue oxygenation in mammals that involves directly applying a composition to skin or mucous membranes that increases "the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO_2" as recited in claim 1. As another example, Taylor et al. does not teach "microbubbles consisting essentially of oxygen in a pharmaceutically acceptable vehicle."

Because Taylor et al. does not teach all limitations of claims 1, 2, 4-7, 10, 11, and 13-19, withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 1, 2, 4-7, 10, 11, and 13-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of Ladin et al (US Patent No. 5,792,090) and further in

[1] Lines 8-11, page 28, describe experimental results in humans in which the majority of human subjects had an increase in subcutaneous pO_2 of at least 30%, and that several subjects had significantly greater increases (i.e., 141%, 130%, 90%, 70%). Several paragraphs within Example 2 describe the sensor inserted into the human subjects to measure subcutaneous pO_2 and line 16, page 30 describes the sensor depth as "controlled between 1 and 3 mm beneath the surface of the skin."

view of Kolta et al (US Patent No. 6,139,876). According to the Office Action, "[t]he expected result would be a method for increasing skin oxygenation by applying a composition of high oxygen concentration to a wound, or burn in a topical application or a bath."

Applicants assert that a *prima facie* case of obviousness cannot be made to reject the pending claims because the combination of references does not teach all the claim limitations present in amended claims 1, 2, 4-7, 10, 11, and 13-19.[2] Amended claim 1 (from which claims 2, 4-7, 10, 11, and 13-19 depend) recites "a superoxygenated composition of oxygen microbubbles consisting essentially of oxygen in a pharmaceutically acceptable vehicle directly to a tissue surface selected from the group consisting of skin and mucous membranes for a time sufficient to increase the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO_2." None of Taylor et al., Ladin, and Kolta teach or suggest the limitation of "to increase the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO_2." Applicants note that Ladin, in contrast, discloses measuring the pressure of oxygen on a probe inserted into the perichondrium that covers the cartilage of a rabbit's ear **after the skin and subcutaneous tissue was removed** (see col. 10, lines 10-26). Physically removing the skin to provide oxygen to the perichondrium which is normally below the skin does not teach an increase in partial oxygen pressure at least two millimeters beneath the surface of a tissue (i.e., skin and mucous membranes).

Based on the foregoing, applicants submit that none of the references cited above teach all the limitations of the present and amended claims, nor do the references suggest modifying their teachings to arrive at applicant's invention. Thus, withdrawal of this rejection is respectfully requested.

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[2]See MPEP 2143. ("To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 448, 20 USPQ2d 1438 (Fed. Cir. 1991)").

Conclusion

The currently pending claims before the examiner are supported throughout the specification and are patentable over the prior art. No new matter has been added. This application is now in full condition for allowance, and such action is respectfully requested.

This amendment is accompanied by a request for a retroactive extension of time. The Commissioner is hereby authorized to charge the fee for the retroactive extension of time as well as any underpayment or to credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-0951.

The examiner is cordially invited to call the undersigned if clarification is needed on any matter within this amendment, or if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,
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